



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

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60 8th Street, N.E.
Atlanta, Georgia 30309

July 19, 2001

VIA FEDERAL EXPRESS

Jonathan B. Fulcher, Managing Member
B & J Seafood L.L.C.
1101 Highway 70 East
New Bern, NC 28560

Warning Letter
01-ATL-67

Dear Mr. Fulcher:

On June 4 & 5, 2001, the Food and Drug Administration (FDA) conducted an inspection of your plant, located at New Bern, North Carolina. During that inspection, our investigators documented serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh crabmeat to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations of concern are as follows:

1. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for fresh crabmeat does not list the critical control points of processing (picking, and packing steps) and finished product storage, for controlling the food safety hazard of *pathogen growth and toxin formation as a result of time/temperature abuse*.
2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor three of the eight areas of sanitation with sufficient frequency to ensure control as evidenced by:
 - a. Prevention of Cross-Contamination from Insanitary Objects - employees failed to wash and sanitize their gloves and knives prior to resuming the picking operation after a break; and employees wearing long loose sleeves were in close proximity to cooked crabs, crabmeat, and product contact surfaces.

- b. Protection of Food and Food Contact Surfaces from Adulteration - condensation from the cooling unit was dripping on cooked crab claws; plastic mesh baskets with cooked crabs were placed on picking tables after being in contact with the rusty floor scale; pickers failed to wash and sanitize their hands after touching unsanitized surfaces prior to resuming the picking operation; and employees failed to wash and sanitize their hands prior to placing cooked crabs on picking tables.
- c. Exclusion of Pests - numerous flies inside the processing area on 6/4/01; and a wall in the cooked crab cooling room had a hole leading to the exterior of the building.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the FDA 483 issued to you at the end of the inspection may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnín, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnín at 404-253-1277.

Sincerely,



Ballard H. Graham, Director
Atlanta District